

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,)	
Plaintiff,)	
)	C.A. No. 21-1015 (JLH)
v.)	
)	
SAREPTA THERAPEUTICS, INC.,)	
Defendant.)	
SAREPTA THERAPEUTICS, INC. and THE		
UNIVERSITY OF WESTERN AUSTRALIA,)	
Defendant/Counter-Plaintiffs,)	
)	
v.)	
)	
NIPPON SHINYAKU CO., LTD. and NS)	
PHARMA, INC.,)	
Plaintiff/Counter Defendants.)	

**DECLARATION OF AMY M. DUDASH
IN SUPPORT OF NS'S RESPONSES TO SAREPTA AND UWA'S
MOTIONS FOR SUMMARY JUDGMENT AND DAUBERT MOTIONS**

Amanda S. Williamson (admitted *pro hac vice*)
Christopher J. Betti (admitted *pro hac vice*)
Krista V. Venegas (admitted *pro hac vice*)
Wan-Shon Lo (admitted *pro hac vice*)
Maria E. Doukas (admitted *pro hac vice*)
Zachary Miller (admitted *pro hac vice*)
Guylaine Haché (admitted *pro hac vice*)
Michael T. Sikora (admitted *pro hac vice*)
110 N. Wacker Drive, Suite 2800
Chicago, IL 60601
Telephone: 312.324.1000 | Fax: 312.324.1001
amanda.williamson@morganlewis.com
christopher.betti@morganlewis.com
krista.venegas@morganlewis.com
shon.lo@morganlewis.com
maria.doukas@morganlewis.com
zachary.miller@morganlewis.com
guylaine.hache@morganlewis.com
michael.sikora@morganlewis.com

Amy M. Dudash (DE Bar No. 5741)
MORGAN, LEWIS & BOCKIUS LLP
1201 N. Market Street, Suite 2201
Wilmington, DE 19801
Telephone: 302.574.3000 | Fax: 302.574.3001
amy.dudash@morganlewis.com

Alison P. Patitucci (admitted *pro hac vice*)
2222 Market Street
Philadelphia, PA 19103
Telephone: 215.693.5000 | Fax: 215.963.5001
alison.patitucci@morganlewis.com

*Attorneys for Plaintiff/Counterclaim Defendant
Nippon Shinyaku Co., Ltd. and Counterclaim
Defendant NS Pharma, Inc.*

Dated: January 12, 2024

I, Amy M. Dudash, hereby declare as follows:

1. I am an attorney at the law firm of Morgan, Lewis & Bockius LLP and counsel for Plaintiff Nippon Shinyaku Co., Ltd. and counter-claim Defendant NS Pharma, Inc. (collectively, “NS”) in the above-referenced matter and submit the instant declaration in support of NS’s Responses to Sarepta and UWA’s Motions for Summary Judgment and *Daubert* Motions.

2. Attached as Exhibit 38 is a true and accurate copy of excerpts of the June 15, 2023 deposition transcript of Stephen D. Wilton, Ph.D.

3. Attached as Exhibit 39 is a true and accurate copy of excerpts of the September 27, 2023 deposition transcript of Sue Fletcher, Ph.D.

4. Attached as Exhibit 40 is a true and accurate copy of excerpts of the November 17, 2023 deposition transcript of Andrew H. Hirshfeld, Esq.

5. Attached as Exhibit 41 is a true and accurate copy of [REDACTED] laboratory notebook entitled [REDACTED] produced by Sarepta, bearing Bates numbers SRPT-VYDS-0156085 – SRPT-VYDS-0156292.

6. Attached as Exhibit 42 is a true and accurate copy of [REDACTED] laboratory notebook entitled [REDACTED] produced by Sarepta, bearing Bates numbers SRPT-VYDS-0158109 – SRPT-VYDS-0158290.

7. Attached as Exhibit 43 is a true and accurate copy of [REDACTED] laboratory notebook, [REDACTED], produced by Sarepta, bearing Bates numbers SRPT-VYDS-0155714 – SRPT-VYDS-0155832.

8. Attached as Exhibit 44 is a true and accurate copy of the [REDACTED]
[REDACTED]

██████████ produced by ██████████, bearing Bates numbers FLETCHER0000226 – FLETCHER0000309.

9. Attached as Exhibit 45 is a true and accurate copy of ██████████ Lab Book ██████████, produced by Sarepta, bearing Bates numbers SRPT-VYDS-0158291 – SRPT-VYDS-0158435.

10. Attached as Exhibit 46 is a true and accurate copy of excerpts of the August 25, 2023 deposition transcript of Abbie Ann Marie Adams.

11. Attached as Exhibit 47 is a true and accurate copy of the ██████████ ██████████ laboratory notebook, produced by Sarepta, bearing Bates numbers SRPT-VYDS-0163133 – SRPT-VYDS-0163301.

12. Attached as Exhibit 48 is a true and accurate copy of excerpts of the November 3, 2023 deposition transcript of Scott E. Kamholz, Esq.

13. Attached as Exhibit 49 is a true and accurate copy of the Rebuttal Expert Report of Christine C. Esau, Ph.D., dated October 11, 2023.

14. Attached as Exhibit 50 is a true and accurate copy of excerpts of the *Markman* Transcript, held on May 3, 2023, before the Honorable Gregory B. Williams.

15. Attached as Exhibit 51 is a true and accurate copy of excerpts of Nippon Shinyaku Co., Ltd., NS Pharma, Inc., and Sarepta Therapeutics, Inc.’s Joint Appendix to Claim Construction Brief for the Wilton/UWA Patents, dated March 20, 2023 [D.I. 171], Exhibit 43, Declaration of Michelle L. Hastings, Ph.D.

16. Attached as Exhibit 52 is a true and accurate copy of the Opening Expert Report of Nathan W. Luedtke, Ph.D, dated September 1, 2023.

17. Attached as Exhibit 53 is a true and accurate copy of the Reply Expert Report of

Nathan W. Luedtke, Ph.D, dated October 27, 2023.

18. Attached as Exhibit 54 is a true and accurate copy of the Expert Report and Disclosure of Mark J. Hosfield, dated September 8, 2023.

19. Attached as Exhibit 55 is a true and accurate copy of excerpts of the July 11, 2023 deposition transcript of Gardner Gendron.

20. Attached as Exhibit 56 is a true and accurate copy of excerpts of the June 28, 2023 deposition transcript of Masaya Toda.

21. Attached as Exhibit 57 is a true and accurate copy of NS Pharma Financial Statement, produced by NS, bearing Bates number NS00091316, marked for identification as Exhibit 10 in the July 11, 2023 deposition of Gardner Gendron.

22. Attached as Exhibit 58 is a true and accurate copy of Nippon Shinyaku Co. Ltd. and NS Pharma, Inc.'s Noninfringement Contentions , dated July 11, 2023.

23. Attached as Exhibit 59 is a true and accurate copy of the Declaration of Gardner Gendron, dated January 11, 2024.

Dated: January 12, 2024

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

Amanda S. Williamson (admitted *pro hac vice*)
Christopher J. Betti (admitted *pro hac vice*)
Krista V. Venegas (admitted *pro hac vice*)
Wan-Shon Lo (admitted *pro hac vice*)
Maria E. Doukas (admitted *pro hac vice*)
Zachary D. Miller (admitted *pro hac vice*)
Guylaine Haché (admitted *pro hac vice*)
Michael T. Sikora (admitted *pro hac vice*)
110 N. Wacker Drive, Suite 2800
Chicago, IL 60601
Telephone: 312.324.1000
Fax: 312.324.1001
amanda.williamson@morganlewis.com

/s/Amy M. Dudash
Amy M. Dudash (DE Bar No. 5741)
1201 N. Market Street, Suite 2201
Wilmington, Delaware 19801
Telephone: 302.574.3000
Fax: 302.574.3001
amy.dudash@morganlewis.com

*Attorneys for Plaintiff/Counterclaim
Defendant Nippon Shinyaku Co., Ltd.
and Counterclaim Defendant NS
Pharma, Inc.*

christopher.betti@morganlewis.com
krista.venegas@morganlewis.com
shon.lo@morganlewis.com
maria.doukas@morganlewis.com
zachary.miller@morganlewis.com
guylaine.hache@morganlewis.com
michael.sikora@morganlewis.com

Alison P. Patitucci (admitted *pro hac vice*)
2222 Market Street
Philadelphia, PA 19103
Telephone: 215.693.5000
Fax: 215.963.5001
alison.patitucci@morganlewis.com

CERTIFICATE OF SERVICE

I, Amy Dudash, certify that on January 12, 2024, I caused a copy of the foregoing document which was filed under seal, to be served via electronic mail on the following counsel of record:

Jack B. Blumenfeld
Megan E. Dellinger
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
mdellinger@morrisnichols.com

Charles E. Lipsey
J. Derek McCorquindale
Ryan P. O'Quinn
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
1875 Explorer Street, Suite 800
Reston, VA 20190-6023
(571) 203-2700

William B. Raich
Michael J. Flibbert
Yoonhee Kim
Yoonjin Lee
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
(202) 408-4000

Alissa K. Lipton
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
Two Seaport Lane
Boston, MA 02210-2001
(617) 646-1600

/s/Amy M. Dudash
Amy M. Dudash (DE Bar No. 5741)